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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/685,338	07/23/96	WANG	L 563.2-5902
			EXAMINER

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SUITE 2000  
6109 BLUE CIRCLE DRIVE  
MINNEAPOLIS MN 55343-9131

33M1/0202

RODRIGUEZ, C	PAPER NUMBER
ART UNIT	12

3306

DATE MAILED: 02/02/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 01/09/98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 11-17, 35-47 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 11-17, 35-47 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. *(Substitute)*  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☒ The specification is objected to by the Examiner.  
☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892  
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3  
☒ Interview Summary, PTO-413  
☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 *(Substitute)*  
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

BEST AVAILABLE COPY

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### **DETAILED ACTION**

Below is included the detailed restriction requirement as mentioned in the Interview Summary filed on January 7, 1998.

#### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
    - I. Claims 1-10 and 29-32, drawn to method of forming a balloon, classified in class 264, subclass 900.
    - II. Claims 11-17, drawn to a balloon, classified in class 604, subclass 96.
  2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as extrusion.
  3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
  4. During a telephone conversation with William Anderson on January 7, 1998 a provisional election was made without traverse to prosecute the invention of Group II, claims 11-17.
- Affirmation of this election must be made by applicant in responding to this Office action.

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Claims 1-10, and 29-32 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

6. Applicant's election of Group II, claims 11-17, 35-47 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

***Oath/Declaration***

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The serial number and filing date of the claimed priority of the U.S. prior application 08/392,837 are incorrect.

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***Specification***

8. The disclosure is objected to because of the following informalities: reference to the application serial number 08/392,837 is incorrect throughout the specification. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

9. Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 depends from the canceled claim 33.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

11. Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al(5,500,180).

Anderson et al. discloses a thermoplastic polymer material balloon, where the thermoplastic polymer material being a block copolymer material.

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***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 12-17, 35-42, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al(5,500,180).

Anderson et al. discloses the invention substantially as claimed. However, Anderson et al. does not disclose all the different variations of inflation pressure and diameter as claimed by Applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Anderson et al. by providing all the different variations of inflation pressure and diameter to the balloon as an obvious design choice by varying and controlling the specifications in the process of making the balloon.

14. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Kaneko et al(5,344,400).

Anderson et al. discloses the invention substantially as claimed. However, Anderson et al. does not disclose the balloon formed from at least two concentric layers of different thermoplastic polymers.

Kaneko et al. teaches a balloon having at least two concentric layers of different thermoplastic polymers for the purpose of stability and flexibility. It would have been obvious to

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one having ordinary skill in the art at the time the invention was made to modify Anderson et al. by providing the at least two concentric layers of different thermoplastic polymers as taught old and well known by Kaneko et al in order to improve the stability and flexibility of the balloon.

15. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Cohen et al(5, 167,239).

Anderson et al. discloses the invention substantially as claimed. However, Anderson et al. does not disclose a method of treating a gastrointestinal lesion having the steps as claimed by Applicant.

Cohen et al. teaches an anchorable guidewire for treating a gastrointestinal lesion having the steps as claimed by Applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute Anderson's et al. catheter and use it for treating a gastrointestinal lesion as taught old and well known by Cohen et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on Monday-Friday from 7:00am to 3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Buiz, can be reached on (703) 308-0871. The fax phone number for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

*CLR 01/23/98*  
Cris L. Rodriguez  
January 23, 1998

*Corrine M. McDermott*  
CORRINE M. McDERMOTT  
PRIMARY EXAMINER  
GROUP 3300